

INDUSTRY WATCH

Old ways, new means: tobacco industry funding of academic and private sector scientists since the Master Settlement Agreement

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When, as a condition of the Master Settlement Agreement (MSA) in 1998, US tobacco companies disbanded the Council for Tobacco Research and the Center for Indoor Air Research, they lost a vital connection to scientists in academia and the private sector. The aim of this paper was to investigate two new research projects funded by US tobacco companies by analysis of internal tobacco industry documents now available at the University of California San Francisco (San Francisco, California, USA) Legacy tobacco documents library, other websites and the open scientific literature. Since the MSA, individual US tobacco companies have replaced their industry-wide collaborative granting organisations with new, individual research programmes. Philip Morris has funded a directed research project through the non-profit Life Sciences Research Office, and British American Tobacco and its US subsidiary Brown and Williamson have funded the non-profit Institute for Science and Health. Both of these organisations have downplayed or concealed their true level of involvement with the tobacco industry. Both organisations have key members with significant and long-standing financial relationships with the tobacco industry. Regulatory officials and policy makers need to be aware that the studies these groups publish may not be as independent as they seem.

When the MSA forced the US tobacco companies to act independently of one another, they were left with three alternative strategies, listed in a memo to Philip Morris Vice President Denise Keane by consultant Jim Tozzi¹⁶:

1. establish a new programme within the individual company;
2. join the efforts of an existing group; and
3. establish a new organisational structure outside of the company.

The Philip Morris External Research Program^{17 18} is an example of a new organisational structure established outside the company. The symposium series on inhalation toxicology funded through the International Life Sciences Institute, by Philip Morris and RJ Reynolds,¹⁹ is an example of joining the efforts of an existing group. We describe two new industry-funded research projects: Philip Morris' research projects on cigarette additives and reduced-risk products through the Life Sciences Research Office (LSRO) and the Institute for Science and Health (IFSH).

METHODS

We located the documents cited in this paper by searching the 45 million pages of tobacco industry documents made public as a result of litigation against the tobacco companies. Between May 2005 and October 2006, we searched the University of California San Francisco Legacy Tobacco Documents Library (<http://www.legacy.library.ucsf.edu>) and Tobacco Documents Online (<http://www.tobaccodocuments.org>), using standard strategies,²⁰ starting with keywords such as "IFSH", "LSRO", and "external research". The initial searches yielded names of projects, research institutions and researchers, which were then searched. We also read the websites of the LSRO (<http://www.lsro.org>) and the IFSH (<http://www.ifsh.org>) and contacted these organisations to ask questions that were not answered on the websites. We found the IFSH Internal Revenue Service 990 forms on <http://www.guidestar.org>.

Many individuals and institutions, particularly in the scientific community, choose not to accept funding from the tobacco industry.^{1–4} Historically, the industry's reasons for funding publishable external scientific research have included building public credibility,^{5–7} developing industry-friendly experts to represent them in litigation and the regulatory process,^{8–11} and creating controversy about the health risks of active and passive smoking.^{7 9–14} Until 1998, almost all tobacco industry funding for academic scientists came through the industry's Council for Tobacco Research (CTR) and the Center for Indoor Air Research (CIAR). These two organisations played a central role in the fraud alleged by the lawsuits brought against the tobacco industry in the 1990s. In the Master Settlement Agreement (MSA) in 1998, the tobacco companies agreed to disband the CTR and CIAR, and cease sponsoring research through industry-wide groups.¹⁵

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Abbreviations: BAT, British-American Tobacco; CIAR, Center for Indoor Air Research; CTR, Council for Tobacco Research; IFSH, Institute For Science and Health; LSRO, Life Sciences Research Office; MSA, Master Settlement Agreement

RESULTS

Life Sciences Research Office

The LSRO was established in 1962 by the Federation of American Societies for Experimental Biology to provide expert opinion on medical issues to the US Army,²¹ and was incorporated as an independent non-profit research organisation in 2001.²² Philip Morris entered into a contract with the LSRO to conduct reviews of and public meetings on cigarette additives, and reviews of the methods necessary to assess potentially reduced-risk tobacco products.²³ Tobacco industry scientists are invited speakers and observers at many of the meetings.^{24–30} The end product of this process was a series of book-length reports, the first two of which (*Evaluation of cigarette ingredients: feasibility*³¹ and *Evaluation of cigarette ingredients: scientific criteria*³²) were available for sale on the LSRO website as of September 2006.³³ The intention of the Philip Morris Worldwide Scientific Affairs group through this project was to “provide a framework for cigarette ingredient review that can become a model for regulatory bodies”.³⁴ In general, Philip Morris intended that the projects with LSRO meet the goals of the 2002 Institute of Medicine Report “Clearing the smoke: assessing the science based for tobacco harm reduction”.³⁵

In its descriptions of these projects on its website,^{23 36} the LSRO states, “In order to preserve the third-party independence of the review, PM will have no role in the design, conduct, deliberations, or the conclusions of the committees/panels.... All private communications between PM and LSRO will be restricted to authorized individuals and will be logged. Private communication between PM and members of the expert panels/expert committees is prohibited.” However, Philip Morris seems to have had more input into the LSRO process than the LSRO’s website description would suggest.

In his initial letter to Philip Morris, outlining the way in which the LSRO would do the proposed cigarette additives project, LSRO director Michael Falk stated that “Expert Review Panel members will be selected for their scientific credentials, absence of bias and conflict of interest, active participation in the field, open mindedness, and willingness to devote the necessary time.”³⁷ The LSRO received and even solicited input from Philip Morris to determine the membership of the panel. A memo from PM scientist Edward Carmines to fellow members of the Worldwide Scientific Affairs Department states:

Attached please find a list of people LSRO is talking to for the SAB [probably the expert panel, since there was no additional scientific advisory board]. They are now evaluating potential conflicts of interest on each of these individuals. Let me know if you have any specific concerns about any of the candidates. I need documentation to provide LSRO with if we feel an individual is not qualified or is biased against the industry.³⁸

Later, the LSRO seems to have asked Philip Morris to suggest an epidemiologist and a cardiovascular toxicologist.³⁹ This level of involvement in choosing the membership of the expert panel on cigarette additives stands in clear contrast with the LSRO’s public statement that Philip Morris would have no role in the design of the committees.

The prohibition of private communication between Philip Morris and members of the expert panels also seems to have been interpreted in a way that would benefit Philip Morris. In a series of emails in December 2001, Philip Morris, scientist George Patskan asked what the sentence “Private communication between PM [Philip Morris] and members of the expert panels will be prohibited”⁴⁰ meant. Carmines replied “I spoke to the LSRO and they do not see a need for clarification. We are restricted from discussing issues with the Board relating only to the charge of the committee. We can use them for other issues.”⁴¹

The cigarette additives project had a single expert panel. The reduced risk project had a “core committee” that integrated the findings of smaller, topic-specific expert panels. The membership of the cigarette additives expert panel and the reduced risk core committee included many individuals who have financial ties with the US tobacco industry, including Philip Morris. Seven of the 15 panel and committee members have documented direct financial relationships with the tobacco industry, and two more have indirect or non-financial relationships. Thomas Slaga was awarded a Philip Morris External Research Program grant in May 2001⁴² and Emmanuel Rubin was an expert witness for Philip Morris on at least two occasions (table 1).

INSTITUTE FOR SCIENCE AND HEALTH

IFSH is a non-profit organisation formed in 2001 that “secures and administers grants for underfunded, under-researched health issues affecting at-risk populations, by forging meaningful collaboration with world-class organizations”⁸² in eight programme areas: tobacco science and health, gastrointestinal disease, neurodegenerative disorders, diseases from airborne contaminants, youth health and development, blood-based diseases, degenerative eye diseases and environmental causes of illness.⁸³ Between October 2001 and September 2004, IFSH received US\$9.5 million and spent US\$3.0 million on their programmes.^{84–86} The vast majority of this money went to tobacco-related research.

The IFSH has sponsored four symposia on tobacco: “Forum on tobacco science and health policy” (St Louis, Missouri, 2001⁸³), “Perceptions and realities in funding health research related to lifestyle factors underlying human disease in the 21st-century” (Prague, Czechoslovakia, 2004⁸³), “Biomarkers of harm, tobacco toxicity, and emerging cancer patterns and etiology” (St Louis, Missouri, 2005⁸³) and “Tobacco harm reduction and perception of risk” (Vienna, Austria, 2006⁸⁷). A symposium on pancreatic cancer is planned for 2006.⁸⁸ Transcripts of the first two tobacco forums and an abstract list from the third were available on the IFSH website, but as of September 2006 we found no publications from these forums on PubMed, Google or Yahoo, searching the titles of the symposia.

From 2002 to 2004, the IFSH granted US\$3.9 million to academic scientists studying biomarkers of tobacco-smoke exposure and harm, tobacco harm reduction and toxicity of tobacco constituents.^{83 89–91} (Some of the grants are multi-year, so this figure does not match with programme expenditures reported to the Internal Revenue Service.) The IFSH also owns and, until 2006, provided online access to a collection of over 510 000 citations on smoking and health.⁹² The cost for managing the citation database was itemised separately in only the 2001 and 2002 reports to the International Revenue Services, equalling US\$670 673 between October 2001 and September 2003.^{84 85}

Of the eight IFSH programme initiatives, six (neurodegenerative disorders, diseases from airborne contaminants, youth health and development, blood-based diseases, degenerative eye diseases and environmental causes of illness) report no activity. In financial years 2001 and 2002, gastrointestinal diseases received 1.4% of the total programme services outlay. The programme services outlays were not itemised in fiscal year 2003. In 2005, the gastrointestinal diseases programme initiative made its first research grants for pancreatic cancer: two 1-year grants⁹⁰ totalling US\$120 000.⁹³

The donor lists for all IFSH programme initiatives include “anonymous private donations” and “IFSH general fund”. The tobacco science and health initiative lists two additional sources of support: British-American Tobacco (BAT) and Brown and Williamson Tobacco (the former US subsidiary of BAT, which subsequently merged with RJ Reynolds). The gastrointestinal diseases initiative lists eight other sources of support: the Ann E McEnroe Pancreatic Cancer Research Fund Program (in honour

Table 1 Tobacco industry relationships of Life Sciences Research Office Cigarette Additives Panel and Reduced Risk Core Committee members

Name	Committee membership	Profession and employers	Relationships with tobacco industry	Published with tobacco company personnel	Pubmed citations on tobacco or cigarette smoke as of September 2006
Alwynelle S Ahl	Cigarette additives (last 2 meetings through the end of project) Reduced risk	Veterinarian Highland Rim Research Organization USDA	None	No	No
Carroll E Cross	Cigarette additives Reduced risk	Tuskegee University Physician/pulmonologist UC Davis	1970–77 CTR grant ^{43–47}	No	28
Donald Gardner	Cigarette additives Reduced risk	Toxicologist US EPA	2000 Consultant (Lorillard) ^{48–49} 1999 Member of Eclipse Report Expert Panel (RJR) ⁵⁰ 1988 Expert witness (Lorillard) ⁵¹ 1987 Applied for position of Executive Director of CIAR ⁵²	Yes ⁵⁰	No
Shayne C Gad	Cigarette additives Reduced risk	Northrop/Mantech Corporation Editor of <i>Journal of Inhalation Toxicology</i> Toxicologist Gad Consulting Services (founder/principal) Becton Dickinson GD Searle	None	No	No
Louis D Homer	Cigarette additives Reduced risk	Allied Corporation Physiologist	None	No	No
Emanuel Rubin	Cigarette additives Reduced risk	Legacy research US Naval Medical Research Institute Pathologist Thomas Jefferson University Hahnemann University Mt Sinai Medical School/Hospital	2000 Expert witness (all US tobacco companies except Liggett) ⁵³ 2000 Expert witness (PM) ⁵⁴ 1997 Expert witness (Lorillard) ⁵⁵ 1996 Expert witness (Liggett) ⁵⁶ 1991 Expert witness (PM) ⁵⁷	No	No
Rudolph Jaeger	Cigarette additives	Toxicologist Environmental medicine New York University CH Technologies (founder/principal)	1999 Member of Eclipse Report Expert Panel on CO (RJR) ⁵⁰ 1995–6 Consultant (RJR) ^{58–59} 1994 Equipment sales (PM) ⁶⁰ 1987–90 Consultant (RJR) ⁶¹	Yes ⁵⁰	No
Robert Orth	Cigarette additives	Chemist Apis Discoveries (founder/principal) Monsanto University of Missouri	None	No	No
Resha Putzrath	Cigarette additives (withdrew from project mid-2003)	Physiologist/biophysicist Georgetown Risk Group (founder/principal) Johns Hopkins University Organization Resources Counsellors Environ Corporation US National Institutes of Health	None	No	1
James L Schardein	Cigarette additives	Toxicologist WIL Research Labs MPI Research/International Research and Development Corporation	1996 MPI performed animal toxicology tests (Lorillard) ⁶² 1979–88 IBD/MPI performed animal toxicology tests (PM) ^{63–66}	No	No
Thomas J Slaga	Cigarette additives	Physiologist/Biophysicist AMC Cancer Research Center, University of Colorado University of Texas Oak Ridge National Laboratories	2001 PMERP research grant ^{42–67} 1999 Member of Eclipse Report Expert Panel (RJR) ⁶⁸ 1987–94 Consultant (RJR) ^{69–72} 1978 ORNL had CTR contract ⁷³	Yes ⁵⁰	3
Elizabeth Anderson	Reduced risk	Chemist Exponent Health Sciences International (founder/principal) US EPA	2000 SI report on phosphine (RJR) ^{74–75} 1998 SI wrote CIAR monograph 1996 ⁷⁶	No	1
Nancy L Buc	Reduced risk	Lawyer Buc Levitt and Beardsley US FDA	1995-present Buc Levitt and Beardsley do pro bono work for the Washington Legal Foundation, a non-profit supported partly by tobacco company donations that litigates against government regulation of tobacco ⁷⁷	No	No
Joseph Rodricks	Reduced risk	Biochemist Environ Corporation (founder/principal)	1986–9 Consultant (RJR) ^{78–79}	No	No

Table 1 Continued

Name	Committee membership	Profession and employers	Relationships with tobacco industry	Published with tobacco company personnel	Pubmed citations on tobacco or cigarette smoke as of September 2006
Richard Schwing	Reduced risk	Risk analyst General motors corporation	1992 Informal (unpaid) consultant (PM) ^{80 81}	No	1
Richard Windsor	Reduced risk	Public health educator	None	No	14

of the IFSH president's late wife), the Debbie Ketterer Memorial Tribute Fund (in honour of a board member's late wife), and six small IFSH fund raisers^{82 94-97} that raised an average of US\$16 683 each.⁹⁵⁻⁹⁷ Thus, it seems that the majority of the \$9.5 million

donated to IFSH between 2001 and 2004 was earmarked for the tobacco science initiative or general operating expenses.

Of the 17 Tobacco Science and Health grants awarded and documented as of September 2006, 15 funded research on

Table 2 Tobacco industry relationships of the Institute For Science and Health Tobacco Science and Health Advisory Council members

Name	Profession Employers	First financial relationship	Published with tobacco company personnel?	Pubmed citations on tobacco or cigarette smoke as of September 2006
Roger Jenkins*	Chemist ORNL	2004 PMERP grant to ORNL ¹⁰⁶ 2001 Consultant to Brown and Williamson ^{101 103} 2000 ETS survey of corp. headquarters (Lorillard) ¹⁰⁷ 2000 Instrument validation (PM) ¹⁰⁸ 1992-9 16-Cities study (CIAR/RJR/ORNL) ^{109 110} 1994 OSHA presentation (CIAR/ORNL/RJR) 1987-90 Develop personal air sampler (CIAR) ¹¹¹⁻¹¹³ 1985 Clove cigarette analysis (RJR) ¹¹⁴ 1976 ¹¹⁵	No	21
John Gorrod	Chemist University of Essex, UK University of London, UK	1998 Paid visit to PM Research Center ¹¹⁶ 1997 Edited monograph on nicotine metabolism (PM) ¹¹⁷⁻¹¹⁹ 1993 Grant (PM/FTR) ¹²⁰ 1992 Paid visit to INBIFO ¹²¹ 1989-94 Postdoctoral fellowships (PM) ^{122 123} 1987 Paid visit to INBIFO ¹²⁴ 1975-78 CTR grant ^{125 126} 1999 Grant (PM/FTR) ¹²⁷ 1994 Grant (PM/FTR) ¹²⁸⁻¹³⁰	No	5
Elmar Richter	Veterinarian Ludwig Maximilians Universitaet, Munich	1999 Grant (PM/FTR) ¹²⁷ 1994 Grant (PM/FTR) ¹²⁸⁻¹³⁰	Yes ¹³¹⁻¹³⁵	31
Dietrich Hoffmann	Chemist AHF	1961-1987 both AHF and the Sloane Kettering Institute received tobacco industry funding for Hoffmann's research ¹³⁶	No	203
Karl O. Fagerstrom	Behavioural Psychologist Fagerstrom Consulting (founder/principal) Pharmacia Corp. University of Uppsala, Sweden	2002 Consultant (Swedish Match) ¹³⁷	No	44
Stephen Rennard	Pulmonologist University of Nebraska Medical Center	1997-8 Grant to test Eclipse cigarette (RJR) ¹³⁸	No	40
Heidi Foth	Toxicologist Halle-Wittenberg University, Germany University of Goettingen, Germany	1991 Speaker at INBIFO ^{139 140}	No	40
Marie Stiborova	Biochemist Charles University, Czechoslovakia	None	No	No
Paula Knudson	Certified IRB Professional University of Texas	None	No	No
Alan J Paine	Toxicologist King's College, London UK Department of Health Toxicology Unit	None	No	No

AHF, American Health Foundation; CIAR, centre for indoor air research; ETS, environmental tobacco smoke; FTR, faculty travel and research; INBIFO, Institut für industrielle und biologische Forschung GmbH; IRB, Institutional Review Board; ORNL, Oak Ridge National Laboratories; PM, Philip Morris; PMERP, Philip Morris External Research Program; RJR, R.J. Reynolds.

*Roger Jenkins is also a member of the IFSH Board of Directors.

What this paper adds

- Before the Master Settlement Agreement (MSA), the tobacco industry funded scientific research through the Council for Tobacco Research (CTR) and the Center for Indoor Air Research (CIAR). Funding scientists through the CTR and CIAR allowed the industry to obtain supportive publicity, recruit “outside” scientists to serve as industry witnesses in lawsuits and regulatory forums, and, ultimately, create false controversy about the science that shows that smoking and secondhand smoke are dangerous.
- Since the MSA, the industry has been funding scientific research. We examine two recent examples: the Life Science Research Office studies on cigarette additives and evaluating potential reduced-exposure products, and studies by a new granting organisation, the Institute for Science and Health.
- Both groups obscure the true extent of involvement of the tobacco industry in their affairs.
- Institutions and individual scientists who choose not to accept industry money need to be aware of both enterprises.
- Regulatory officials and policy makers need to be aware that the studies these groups publish may not be as independent as they seem.

biomarkers, one on potential reduced exposure products, and one on chemopreventive agents for oesophageal cancer.^{89–91} The chemoprevention research grant was from a fund separate from the other tobacco science grants, the Dietrich Hoffmann Career Development Award, and provided 1 year of support at US\$40 000.⁹⁴

Like LSRO, the IFSH presents itself as “independent”; as of 2005, its website stated:

The Institute is independent, a critical factor in maintaining the credibility and integrity of research. A proprietary process is used to manage the overall research process. This process creates a firewall between the Institute’s sponsors and the researchers to whom the Institute supplies grant funding.⁹⁸

Likewise, the Request for Applications states:

The Institute’s Board of Directors and the respective Advisory Council consider all offers of support before an offer of support is accepted. The Institute’s criteria for accepting grants from a given grantor require that the Institute’s credibility can be insured, so that the Institute can function completely independently of the grantor, for example, through unrestricted grants. The Institute, in turn, makes grants to external organizations and individuals.⁹³

The grant from BAT and Brown and Williamson is described as unrestricted in the Tobacco Science and Health Request for Applications.⁹⁹ The Tobacco Science and Health Advisory Council reviews the proposals received, selects proposals to be reviewed, chooses the three outside reviewers each is sent to, and then decides which proposals to fund.^{93 100}

Although there is no obvious direct involvement of the tobacco industry in the granting process at IFSH, 7 of the 10 scientists on the Council had documented direct financial

relationships with the tobacco industry (table 2). Roger Jenkins, who had been funded almost continuously by the tobacco industry between 1992 and 2006 (the time this paper was written), was a consultant to Brown and Williamson the year before he was appointed to the IFSH Tobacco Science and Health Advisory Board.^{101–103} Jenkins was appointed to the IFSH Board of Directors in 2004, and served on both the Board of Directors and the Tobacco Science and Health Advisory Board as of September 2006 (table 2).^{104 105}

Donors and applicants to the other programme initiatives at IFSH may not know that the majority of the funds the IFSH administers go to research on tobacco. Brown and Williamson and BAT are not listed on the home page or in the IFSH promotional video on the home page. The 10 min video describes IFSH’s mission as “to be involved in orphan diseases” and lists Graves’ disease, retinitis pigmentosa, Guillain-Barré syndrome, torticollis, neurodegenerative disorders, amyotrophic lateral sclerosis, attention deficit hyperactivity disorder, Krabbe disease, pancreatic cancer, cerebral palsy, macular degeneration, multiple sclerosis, lupus, Tourette syndrome, tuberculosis and diseases from airborne contaminants.¹⁴¹ Two slides, titled “Adult current smoking among women” and “Adult current smoking by age group & year” are on the screen for 3 s, while a grantee praises the Institute’s support for innovative research.¹⁴¹ The only discussion of tobacco is when the narrator says, “Before Ann McEnroe was even diagnosed [with pancreatic cancer], the Institute was supporting innovative and extremely necessary work to prevent disease: early diagnosis, risk factors, diet, *smoking* (emphasis added), environmental conditions affecting the health and well-being of everyone”.¹⁴¹ The focus, in their video, on pancreatic cancer and the diseases that IFSH hopes to fund, combined with the omission of discussion on the significant body of research it already has funded, minimises the role of funding from Brown and Williamson in their affairs.

DISCUSSION

When the US tobacco companies signed the MSA, they lost one of their primary economic and social relationships with scientists in academia. Since the 1930s, the US tobacco industry has recognised the strategic and financial importance of positive relationships with scientists, universities, journals and scientific societies.⁵ Funding academic scientists through the CTR and CIAR allowed the industry to obtain supportive publicity,^{6 7} recruit “outside” scientists to serve as industry witnesses in lawsuits and regulatory forums,^{8–10} and, ultimately, create false controversy about the science that shows that smoking and second-hand smoke are dangerous.^{7–14} The CTR and CIAR were publicly represented as independent, while in fact both were closely controlled by industry scientists and lawyers.^{7 110 142}

The LSRO and IFSH are not exactly the same as the CTR and CIAR, but they do continue many of their functions. Both provide opportunities for professional and social interaction between industry personnel and academic researchers, which may help the industry identify and recruit future witnesses and consultants, the LSRO through its meetings^{25 143 144} and the IFSH through its conferences.^{145–147} The LSRO’s interpretation of the contract to prohibit only private communication between LSRO panel and committee members and tobacco industry employees regarding committee business would also permit such recruitment.

Both the IFSH and the LSRO also obscure the true extent of involvement of the tobacco industry in their affairs. The Philip Morris LSRO project²³ makes explicit claims of independence¹⁴⁸ that are contradicted by the internal tobacco industry correspondence indicating that the LSRO gave Philip Morris a chance to suggest potential panel members³⁹ and at least to comment on the potential members of the LSRO scientific

panels.³⁸ In all, 54% of the members of the Cigarette Additives Expert Panel and 44% of the members of the Reduced Risk Core Committee have documented direct financial relationships with the US tobacco industry (table 1). Some of these relationships date back decades and may provide a potential conduit for the tobacco industry's input into LSRO committee reports.

Although 97% of the funds the IFSH granted in 2001–5 support tobacco research and seem to come from BAT and its former US subsidiary, Brown and Williamson, the IFSH home page and promotional video do not mention these companies or discuss the tobacco research they fund. This obscures the connection between the IFSH and the tobacco industry. The fact that IFSH Tobacco Science and Health Council and Board of Directors member Roger Jenkins was consulting for Brown and Williamson just prior to the time the IFSH was founded provides a potential conduit for Brown and Williamson's input into IFSH's granting decisions.

Institutions and individual scientists who do not want to accept industry money,^{1,4} and members of the public who do not want to donate to organisations funded primarily by the tobacco industry need to be aware of the new organisations the industry is channelling funding through. Regulatory officials and policy makers need to be aware that the studies being published on issues relevant to the industry, such as cigarette additives and "potentially reduced harm products", may not be as independent as they seem.

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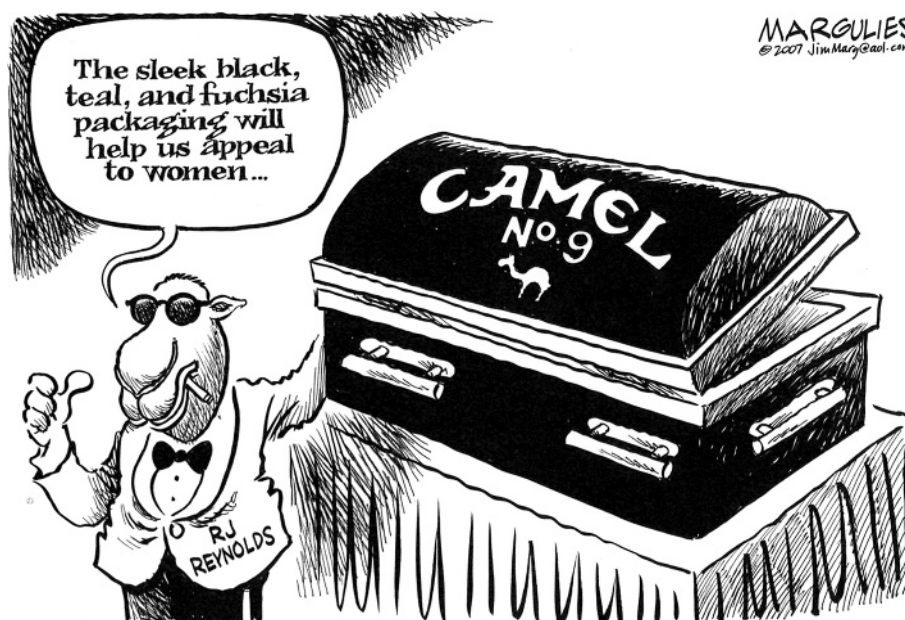
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